510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K033051

B. Analyte:
Legionella IgG/IgM antibodies

C. Type of Test:
(ELISA) Enzyme Linked Immunosorbent Assay

D. Applicant:
Trinity Biotech USA

E. Proprietary and Established Names:
Trinity Biotech Captia™ Legionella pneumophila IgG/IgM ELISA Test System

F. Regulatory Information:

1. Regulation section:
   21 CFR Part 866.3300 Haemophilus spp. Serological reagents
2. Classification:
   Class II
3. Product Code:
   MJH – Legionella spp. ELISA
4. Panel:
   83

G. Intended Use:

1. Intended use(s):

The Trinity Biotech Legionella pneumophila IgG/IgM Enzyme-Linked Immunosorbent Assay (ELISA) is intended for the qualitative detection of total antibodies (IgG and IgM) to Legionella pneumophila (Legionella) serogroups 1-6 in serum from patients with clinical suspicion of Legionella Disease.

2. Indication(s) for use:

The Legionella pneumophila IgG/IgM ELISA kit is an Enzyme-Linked Immunosorbent Assay (ELISA) for the qualitative detection of total antibodies (IgG and IgM) to Legionella pneumophila serogroups 1-6 in serum from patients with clinical suspicion of Legionella Disease. The assay is not intended to differentiate between the serotypes of Legionella.

3. Special condition for use statement(s):
   Not applicable
4. Special instrument Requirements:
   Single or dual wavelength microplate reader with a 450 nm filter.

H. Device Description:

Each kit contains 96 test devices, consisting of Legionella antigen to serogroups 1-6. Purified Legionella pneumophila antigen is attached to a solid phase microtiter well. Diluted test sera is added to each well. If the antibodies are present that recognize the antigen, they will bind to the antigen in the well. After incubation the wells are washed to remove unbound antibody. An enzyme labeled anti-human IgG/IgM is added to each well. If antibody is present it will bind to the antibody attached to the antigen on the well. After incubation the wells are washed to remove unbound conjugate. A substrate solution is added to each well. If enzyme is present the substrate will undergo a color change. After an incubation period the reaction is stopped and the color intensity is measured photometrically, producing an indirect measurement of specific antibody in the patient specimen.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   Wampole Legionella
2. Predicate K number(s):
   K 963318
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Qualitative detection of total antibodies (IgG and IgM) to Legionella pneumophila (Legionella) serogroups 1-6 in serum from patients with clinical suspicion of Legionella disease.	Qualitative determination of IgG and IgM antibodies in human serum to Legionella in patients with clinical signs and symptoms of Legionella disease.
Reagents	Horseradish-peroxidase (HRP) conjugate Goat anti-human IgG/IgM Sample diluent Tetramethylbenzidine (TMB) substrate Wash buffer Stop solution (H2SO4)	Horseradish-peroxidase (HRP) conjugate Goat anti-human IgG/IgM Sample diluent Tetramethylbenzidine (TMB) substrate Wash buffer Stop solution (H2SO4)
Technology	ELISA	ELISA
Calibrators	High and Low positive, negative	High and Low positive, negative
Differences		
Item	**Device**	**Predicate**
None	None	None

J. Standard/Guidance Document Referenced (if applicable):

Not applicable

K. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not Applicable. Performance characteristics and substantial equivalence were previously established in the Wampole predicate device (K963318). The submission was submitted for a name and address change.

b. Linearity/assay reportable range:
Not applicable

c. Traceability (controls, calibrators, or method):
Not applicable

d. Detection limit:
Not applicable

e. Analytical specificity:
Not applicable

f. Assay cut-off:
Not applicable

2. Comparison studies:

a. Method comparison with predicate device:
Not applicable

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a and b are not applicable):
Not applicable

4. Clinical cut-off:
Not applicable

5. Expected values/Reference range:
Not applicable

L. Conclusion:

The Trinity Biotech Captia™ Legionella pneumophila IgG/IgM ELISA Test System is substantially equivalent in performance to the predicate device.